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09/910,639	07/20/2001	Daniel A. Vallem	09531-023001 / Z01015	2607

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EXAMINER

JONES, DAMERON

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,639

Applicant(s)

VALLERA ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-21, 23-29 and 40-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19, 25, 42, 47 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23, 26-29, 40, 41, 43-45, 48 and 49 is/are rejected.
- 7) ☒ Claim(s) 24, 46 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 12/6/04 wherein claims 17, 22, and 30-39 were canceled; claims 18, 24, 25, 27, 29, and 40 were amended; and claims 41-51 were added.

Note: Claims 1-16, 18-21, 23-29, and 40-51 are pending.

RESPONSE TO APPLICANT'S INVENTION

2. The Applicant's arguments filed 12/6/04 to the rejection of claims 18, 20, 21, 23, 24, 26-29, and 40 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part.

112 Rejection

The 112 rejection is WITHDRAWN because Applicant has made amended/canceled the appropriate claims.

103 Rejection

The rejection is being WITHDRAWN on the basis that Applicant has amended the claims to delete the radionuclides encompassed by Pastan et al. However, a new combination rejection is made below using Pastan et al to illustrate that the radionuclide of the newly amended claims are obvious as well.

WITHDRAWN CLAIMS

3. Claims 1-16, 19, 25, 42, 47, and 51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

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NEW GROUNDS OF REJECTIONS

112 Rejections

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 41 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41, line 9: The claim as written is ambiguous because in lines 1-2 of the claim, the type of method is set forth (a method of delivering a radiolabeled immunotoxin to a subject); however, in the last line of the claim, it is stated that the method is killing a target cell in a subject which is not the same as the method initially set forth in the claim. Please clarify in order that one may readily ascertain what is being claimed.

Claim 48, line 10: The claim as written is ambiguous because in lines 1-2, it is stated that the method delivering a radiolabeled immunotoxin to a subject; however, the last line of the claim states that the method is an imaging method which is not the same as that initially set forth. Please clarify in order that one may readily ascertain what is being claimed.

103 Rejections

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 18, 20, 21, 23 26-29, 40, 41, 43-54, 48, and 49, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastan et al (US Patent No. 5,990,296) in view of Goldenberg (US Patent No. 5,332,567) in further view of Jagtap et al (US 2002/0095044) and Kuo (US Patent No. 5,476,866).

Pastan et al disclose single chain Fv regions of the monoclonal antibody and uses thereof (see entire documents, especially, abstract). The tumor specific antibody fragments may incorporate fragments such as immunotoxins which have tumor specificity and which may be used to treat cancer (column 1, lines 13-20; column 2, lines 51-59; columns 10-11, bridging paragraph). In addition, Pastan et al disclose a method of killing or inhibition the growth of cells bearing a Lewis^Y antigen wherein the subject is administered a pharmaceutical composition comprising a fusion protein (column 3, lines 50-55). The effector molecule (targeting agent) may be diphtheria toxin (column 9, lines 8-18). The antibody may be joined to the effector molecule (column 9, lines 50-62). The term 'diphtheria toxin' (DT) encompasses the full length native DT or a DT that has been modified (column 10, lines 16-38). The antibody may be conjugated to various labels to produce a highly specific detectable marker that may be used to detect the presence or absence of cells or tissues bearing the particular molecule to which the antibody is detected (column 11, lines 4-11). The antibodies may be derived from monoclonal antibodies designated as B1, B3, and B5 which have been shown to

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specifically bind carbohydrate antigens that are typically found on various carcinomas including carcinomas of the breast, colon, cervix, and prostate (column 11, lines 57-62; column 18, lines 56-68; column 20, lines 38-50). Labels may be conjugated to the antibody either directly or through a linking molecule. Detection of the antibody bound label depends on type of label (spectroscopic, photochemical, biochemical, immunochemical) attached (column 19, lines 20-37). While Pastan et al disclose a method of delivering a immunotoxin composition to a subject, the reference does not disclose various possible labels as set forth in claim 29, for example.

Goldenberg discloses the detection, imaging, and treatment of infections using immunoconjugates comprising an antibody conjugate (see entire document, especially, abstract). The immunoconjugates comprise an immunoreactive component having at least one substantially monospecific antibody or antibody fragment conjugated to at least one diagnostic or therapeutic agent, wherein the antibody or antibody fragment binds to an epitope of the pathogen or of a pathogen-associated antigen (column 2, lines 47-55). The immunoconjugates are also effective diagnostic agents for scintigraphic imaging or magnetic resonance imaging (column 3, lines 59-64). The imaging agent may comprise a bispecific, trispecific, or polyspecific antibody/antibody fragment conjugates that optionally comprise an imaging radioisotope or paramagnetic species (column 4, lines 62-66). The immunoconjugates may be labeled with metals such as Dy, Gd, or Mn to name a few (column 11, lines 6-23; column 18, lines 17-25).

It would have been obvious to one of ordinary skill in the art to modify the invention of Pastan et al using the teachings of Goldenberg and generate a method of

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delivering a radiolabeled immunotoxin to a subject because Pastan et al disclose immunotoxins that may be radiolabeled which have tumor specificity and may be used in the treatment of mammalian cancer. Goldenberg is cited to illustrate that various radiolabels may be attached to the immunoconjugate for imaging and other purposes (e.g., column 11, lines 6-23; column 18, lines 17-25). Since both Goldenberg and Pastan et al are directed to immunotoxins that may be radiolabeled, the references may be considered to be within the same field of endeavor. Thus, the references are combinable.

It should be noted that both **Kuo et al** and **Jagtap et al** which are directed to pharmaceuticals are cited only to illustrate that inflammation encompasses cancers. For example, Jagtap et al pages 3-4, paragraph [0055], disclose that inflammation may be associated with an inflammatory disease which refer to a disease or condition wherein there is an inflammation of the body tissue. Examples of such diseases/conditions include arthritis, Huntington's disease, and lupus to name a few, as well as other diseases that have significant inflammatory components such as cancer. Thus, a reference disclosing inflammation would contain teachings applicable to cancers as well. Kuo et al disclose compositions useful for treating tumors are also useful for treating inflammatory diseases such as graft versus host disease and cancer (column 3, lines 14-19). Hence, it would be obvious to one of ordinary skill in the art to interchangeably use compositions for inflammatory diseases for cancers as well since cancer is considered in the art as an inflammatory condition.

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CLAIM OBJECTIONS

8. Claims 24, 46, and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: It is once again noted that Applicant's elected species is allowable over the prior art of record (elected species: toxic domain is diphtheria toxin; targeting molecule is Her-2/Neu; and the radionuclide species is ^{64}Cu) because the prior art neither anticipates nor renders obvious claims having the specific limitations as claimed by Applicant.

COMMENTS/NOTES

9. Examiner's comments regarding the phrase 'subject suspected of having a cancer' is noted. However, because a clear definition for the phrase is not set forth in the specification as to what signs/symptoms or precisely what Applicant intends the phrase to encompass, the broadest interpretation possible is utilized. Thus, a subject who is administered a composition encompassed by the instant invention would be one that meets the requirements of a 'subject suspected of having cancer'. Furthermore, if Applicant is using an antibody or fragment thereof that is known to bind cancer receptors, a prior art document administering the same antibody composition would inherently bind cancer receptor like Applicant's invention since similar/like compositions would be expected to possess the same/similar properties/characteristics.

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10. It is once again noted that Applicant's elected species is allowable over the prior art of record (elected species: toxic domain is diphtheria toxin; targeting molecule is Her-2/Neu; and the radionuclide species is ^{64}Cu). The search was expanded to the conditions wherein the toxic domain is diphtheria toxin; any radionuclide; and sFv of the monoclonal antibody B3. The search was not further expanded since prior art was found which could be used to reject the claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

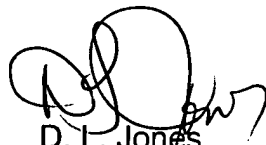
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

March 7, 2005